ARTIFICIAL INTELLIGENCE IN HEALTHCARE ESTABLISHMENTS: A CRITICAL LEGAL ANALYSIS OF LIABILITY FRAMEWORK

A

SYNOPSIS

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IN

LAW

BY

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Year 2025

Candidate's Declaration

I, Divesh Chauhan declare that the synopsis entitled, ***"Artificial Intelligence in Healthcare Establishments: A Critical Legal Analysis of Liability Framework"*** being submitted in the partial fulfillment of the requirement for the award of the degree of Doctor of Philosophy in Law under ICFAI Law School, The ICFAI University, Dehradun during the academic year 2025-26.

It is the work that is expected to carried out under the supervision of **Prof. (Dr.) Arun Kumar Singh**

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ABSTRACT

The integration of Artificial Intelligence (AI) into healthcare systems transformed the medical diagnostics, treatment planning, surgical precision, and administrative operations etc. Where traditional healthcare was more human centric and based on the reason of medical practitioner, the digitalization integration has changed the working whereas, now AI-driven technologies now play a critical role in enhancing patient outcomes and operational efficiency. However, the rapid deployment of autonomous and semi-autonomous systems has outpaced the evolution of legal frameworks specifically related to accountability and liability issue for AI-induced harms. Traditional legal model of liability, such as medical negligence and product liability, remain ill-equipped to respond to the complex, multi-stakeholder environment created by AI in healthcare. This research aimed to Investigate the application of AI in healthcare with its potential benefits and emerging legal risk associated with the adoption of these technologies. Further, with the application of Doctrinal and Empirical methodology the study aims to examine the present regulations for the adoption of AI in healthcare for various purpose to develop a comprehensive understanding around the AI in healthcare establishment. The study also embedded to find out the answer of Who would be liable if harm is cause while applying the AI in healthcare in case of surgical and non- surgical process while applying the traditional liability model and comparative analysis. The expected outcome of this research will contribute to understanding of responsible Adoption and use of AI in healthcare sector for various task and services as well as the legal aspect of the integrating of AI. The well-founded liability model that accommodates AI's technical complexity while ensuring patient safety, legal clarity, and innovation sustainability will enable the fields of cyber law, medical jurisprudence, and AI governance, to understand the both theoretical insights and practical policy recommendations.

Keywords- *Artificial intelligence, Healthcare, Liability, Medical negligence*

1. INTRODUCTION

The advancement to emerging technology and Artificial intelligence changing the various industries and created the basis of fourth revolution which is create the smart entities and smart process. AI is recorded as the new electricity of the emerging revolution *Velarde, G. (2020)*. This transformation is supported by substantial advancements in data availability, advanced algorithm design, and processing power led to the widespread adoption of AI technologies in various fields resulting in faster and more convenient human life and work and unparallel developed and deployed in range of sector. *Bottomley, D., & Thaldar, D. (2023), Naidu, G. and Krishnan, V. (2025)*

Healthcare sector is one of the emerging sectors where AI is expanding its branches, earlier the healthcare relied heavily on the manual diagnosis treatment methods which use to limit the scalability and efficiently *Esteva et al. (2019).* However, the emerging technology has totally changed the working of healthcare sector, as per the 2024 report the healthcare companies in the US are either using or willing to adopt the artificial intelligence, where the adoption of such technology has increased form the per COVID-19 era which recorded as 45% jump. In India over 82% of pharmaceutical and life science companies has adopted the AI to streamline the work and provide the better services where the 36% has been adopted by the MedTech firms [see figure 1] and this adoption is expected increase to 1.6-billion-dollar market by the end of 2025. In Europe the 42% of healthcare organizations using AI for the various task and 19 % are planning to include in upcoming years. This data presents that the adoption of AI is no longer a fictional concept where computer treat the patient and take decision on behalf of medical practicians.

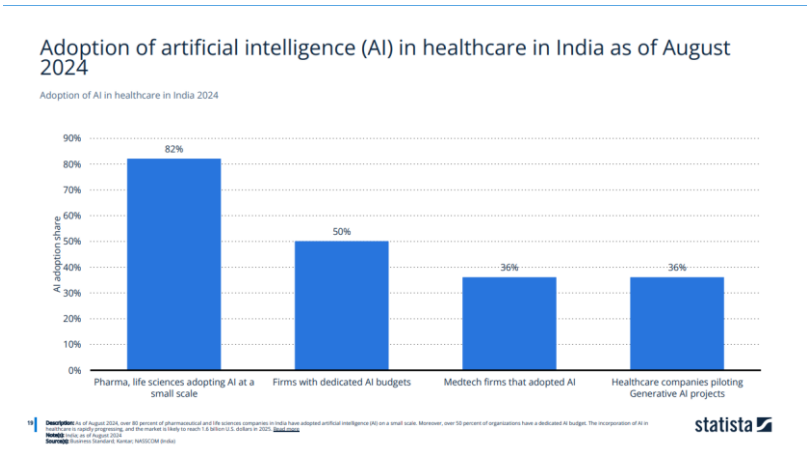

Figure 1 Adoption of AI in Healthcare in India

The Artificial intelligence or AI is defined as the as a system that possesses the ability to think, act, and rationalize in a manner reminiscent of humans, it encompasses both cognitive and behavioral abilities and holds the capability to train itself and store personal experience to further enhance its capabilities which makes it different from the conventional computer algorithms *Maclure, J. (2021).*, *Čerka, P., Grigienė, J., & Sirbikytė, G. (2015)*. Where in the broader term it a branch of computer science aims to substitute the Human intelligence using advance computer algorithm. The subset of AI includes the ML (Machine learning) and DL (deep learning) [See Figure 2] *Alhejaily, A.G. (2025).*

Based on working the intelligence AI is classified into three categories 1) Artificial narrow intelligence or weak AI 2) Artificial general intelligence (AGI) or Strong AI and 3) Artificial Super Intelligence (ASI) *Fauzan et al., (2021*). The European Union has provided a comprehensive definition of AI in legal terms "An AI system is a machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that for explicit or implicit objectives, infers from the input it receives, how to generate output such as prediction, content, recommendations or decision that can influence Physical or virtual environment" *European Parliament. (2024).* AI can learn activities that are beyond the capabilities of humans and work autonomously *Abdullah, A., & Manap, N. A. (2021).*

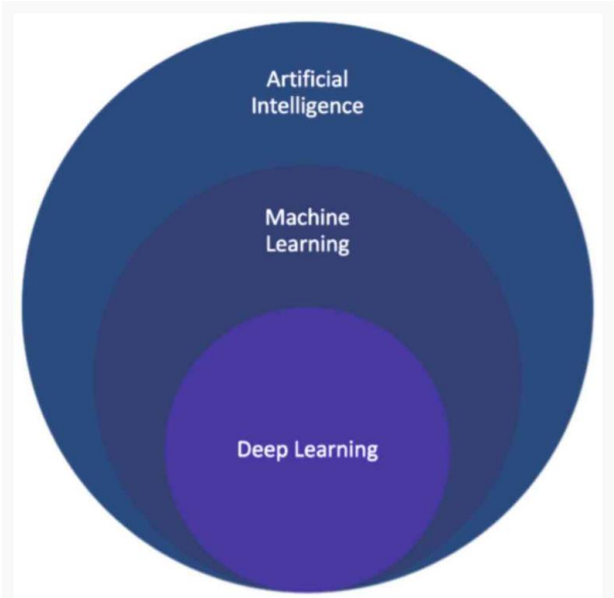

Figure 2 subset of Artificial intelligence

1.1 Application of AI in Healthcare sector

Artificial intelligence (AI)-based algorithms have been widely employed in healthcare. Healthcare utilizes AI and associated technologies, becoming increasingly prevalent in every aspect of our lives. These technologies transforming many aspects of patient care and Operational procedure and withing healthcare providers *Saadat et al, (2024).* The application of AI in healthcare sector cannot be left unseen as the Adoption of AI in healthcare is increased over the period of time, it has changed the working of healthcare with the advance decision-making technique. The AI possess the potential to advance the diagnose, treatment, monitoring and operational aspect. The AI algorithms shift through the vast datasets to identify the patters and predict the treatments for the patients and leap with the personalized medicine. Whereas the application of the AI is not limited to the diagnosis its extent to the various task as shown in the [Figure 3]. This include the use of AI in Diagnostic assistance- where the AI tools analyse the X rays, MRI scan and CT scan to detect the diseases such as tumor, fractures etc. it excels the deep insights into the certain conditions.

Treatment personalization- includes the application of AI to tailored the patient on the basis of pre trained dataset. In drug development the AI accelerates the testing and prediction of the different

chemical compounds which helps to speed up the drug delivery and reduce the time.

Healthcare operations- the AI applications also including in operations such as billing, patient triage, appointment scheduling which improve the efficiency, reduce the cost and enhance the patient satisfactions. Patient monitoring and care- is another aspect of application of AI where the AI include in the wearable technology and remote monitoring. Here, the AI monitor the real time data and helps to understand the health status with the personalized health recommendation *Udegbe et al.*, (2024) and *Abbasgholizadeh et al., (2021).*

Figure 3 Application of AI at various département in healthcare

While the application of AI in healthcare creates the efficiency and reduce the time it also provides the several other benefits as shown in [figure 4], the Ai system find the pattern and make the predictions it also claims to reduce the demand in healthcare and enable the health professionals to manage the existing demand of caser and improve the outcomes. The Potential of AI include the precision and personalization where the AI helps to understand the diseases in more effective way and provide the better treatment. Efficiency and better productivity are another potential, the Application of AI in imaging and clinical decision making give the edge to healthcare professional. Prevention and early detection outcome of AI used software examine the various factors to identify the patients or patient groups at higher risk.

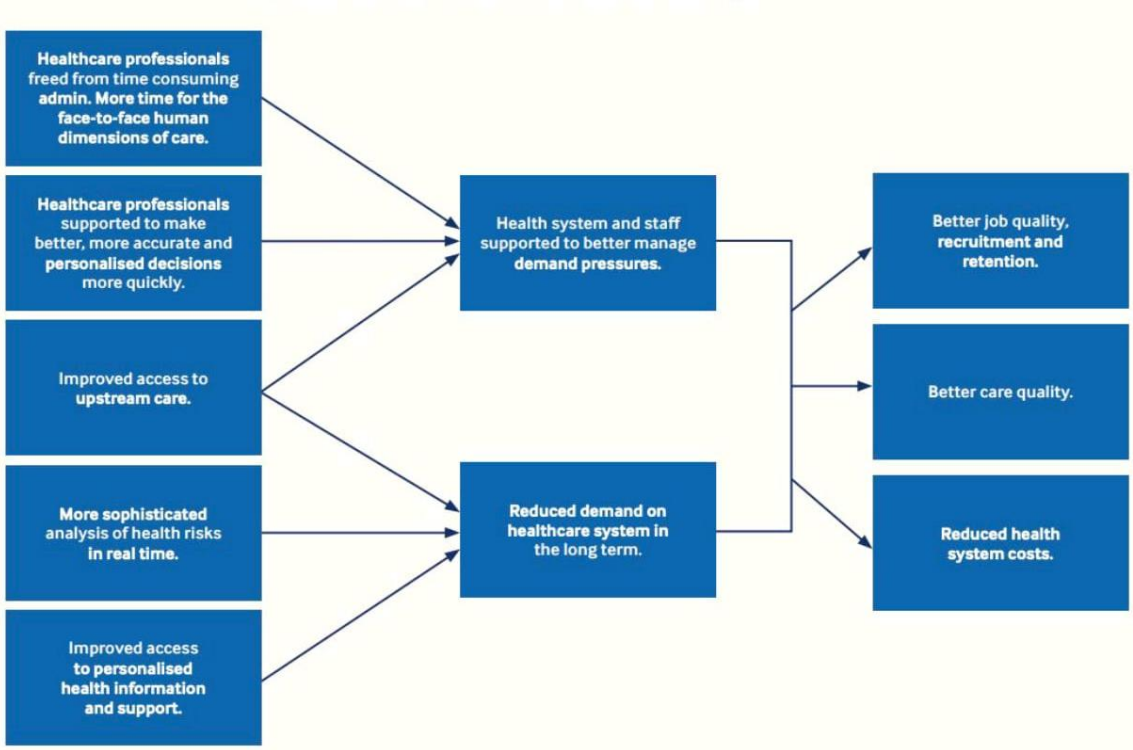
Healthcare professionals freed from time consuming admin. More time for the face-to-face human dimensions of care.
Healthcare professionals supported to make better, more accurate and personalised decisions more quickly.
Improved access to upstream care.
More sophisticated analysis of health risks in real time.
Improved access to personalised health information and support.
Health system and staff supported to better manage demand pressures.
Reduced demand on healthcare system in the long term.
Better job quality, recruitment and retention.
Better care quality.
Reduced health system costs.

Figure 4- Potential outcome of AI application in healthcare

1.2 Legal Risk and Challenges assassinated with Adoption of AI in healthcare

The adoption of new AI technologies by healthcare establishment for various administrative, surgical and non-surgical process raised the various question on the Responsible governance of these technologies and their adoption and implementation. Where one side these technologies have the potential benefits one the other side it also possesses the risk, such as risk of misdiagnose, scope of biasness, question of Data breach, question on Accountability and the liability. *Oniani, D., Hilsman et al., (2025)* discussed that traceability, reliability, lawfulness, accountability, governability, and equity are the important ethical principle [see Figure 5]. Where on the other side the Hallucination are coming up as another issue in LLM model, where the misinformation with the AI model can influence the diagnostic reasoning, recommendation and patient counseling's. *Kim et al., (2025) The* medical Hallucination in LLM is divided into 5 categories [see figure 6]

(a) Factual Errors: this includes the Hallucinations arising from incorrect or conflicting factual information, encompassing Non-Factual Hallucination, Factual Hallucination, and Input-Conflicting Hallucination.

(b) Outdated References: which means the Errors stemming from reliance on obsolete guidelines or data, illustrated by Memory-Based Hallucination.

(c) Spurious Correlations: this include the Hallucinations that merge or misinterpret data in ways that produce unfounded conclusions, including Bias-Induced Hallucination, Amalgamated Hallucination, and Multimodal Integration Hallucination.

(d) Fabricated Sources or Guidelines: Inventions or misrepresentations of medical procedures

and research, covering Procedural Hallucination and Research Hallucination.

(e) Incomplete Chains of Reasoning: the Flawed or partial logical processes, such as Reasoning Hallucination, Decision-Making Hallucination, and Diagnostic Hallucination.

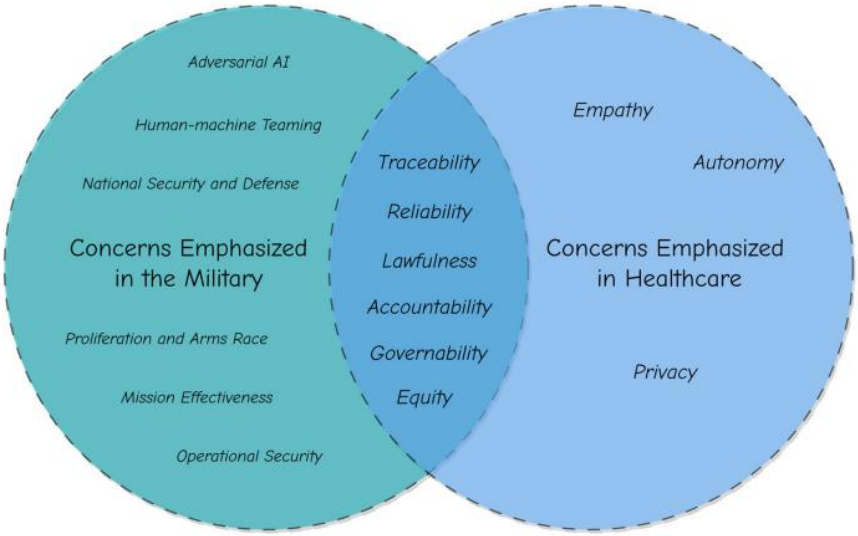

Figure 5- Important Ethical principle using AI in healthcare

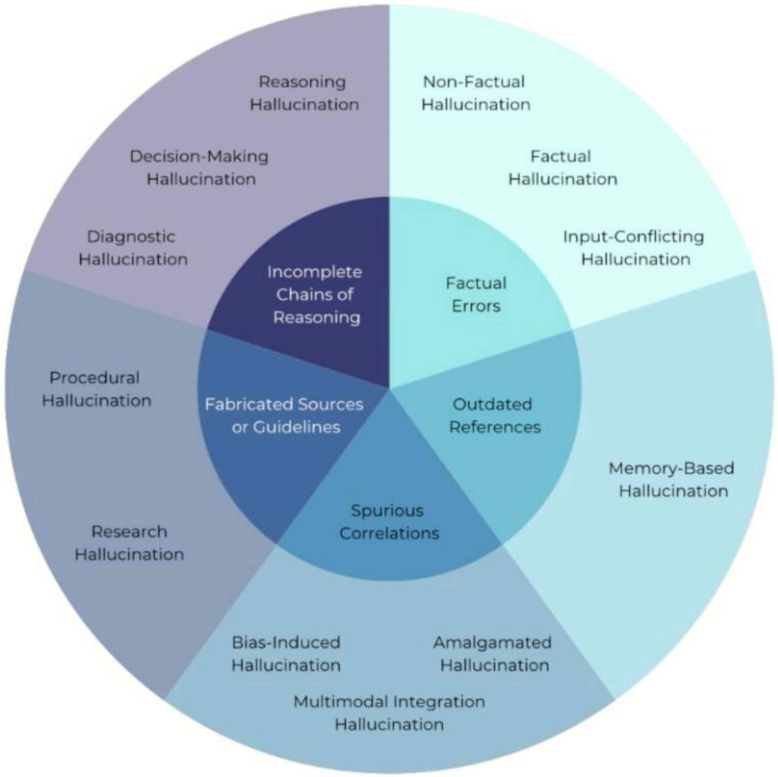

Figure 6- Hallucination of Using AI in healthcare

All these issues are pointing the arrow in one direction the *issue of Liability*, who would be liability if due to a number of reasons, the harm caused to patient, where earlier the policymaker use of adopt the ***harm-based approach*** the inclusion of these technologies converted this into the ***Risk based approach*** to adopt the new policies and framework. Using AI software in clinical settings puts health providers and professionals at greater risk of liability. Appropriate legal advice is required to

address the question of who bears responsibility when safety and quality problems result from the usage of AI medical software. Current rules pertaining to medical malpractice or carelessness recorded not be able to handle this situation and are not yet tested in the context of using autonomous or semiautonomous medical software, if they are at all. *Reddy et al., (2020)*

The Liability is a key concept in the theory of legal science and its reasonable and appropriate use at home and abroad is an important way to strengthen the legal system. *Sullivan, H. R., & Schweikart, S. J. (2019)* and *Price, W. N., Gerke, S., & Cohen, I. G. (2019)*. In law the term "legal responsibility" refers to the liability of an individual for their actions or failure to act. This duty commonly leads to imposition of damages, fines or penalties *Smith, H. (2021*). Different legal scholars have defined liability differently in various contexts. Extract On Salmond's Personal Theory of Obligation Summse-43302 (2) Liability, in Salmond's juristic sense of the term, is the tag word for the juristic personal relationship which arises when a wrong is done. Austin defined liability due consequences that a wrongdoer should suffer because of his breach of duty/act.

In tradition Liability regime this classified into two major categories, i.e., Civil and Criminal and various other Liability approach emerged from the doctrine and legal principles [see figure 7]. Where Civil liability is "the potential for responsibility of payment to an aggrieved party to another for loss or damage." This includes all types of tort liability (negligence, defamation, (etc.) and intentional liability and breach of contract. The aforesaid liability is meant to ensure that the aggrieved party is provided for a redress in the form of pecuniary compensation as well as for the losses *Tobia, K., Nielsen, A., & Stremitzer, A. (2021) and Khullar et al., (2021).* when, the criminal liability is the result of infringement of the criminal laws providing penalties regarding fines, imprisonment and in the extreme cases the death sentence. In such incidents, the state is acting against the tortfeasor to impose punishment *Kim et al (2022)*. However, in case of adoption of AI the concept of liability got changed due to the involvement of various stakeholder as shown in [figure 8], which collective make the use of AI in surgical and non-surgical.

Figure 7- Various Traditional liability approach.

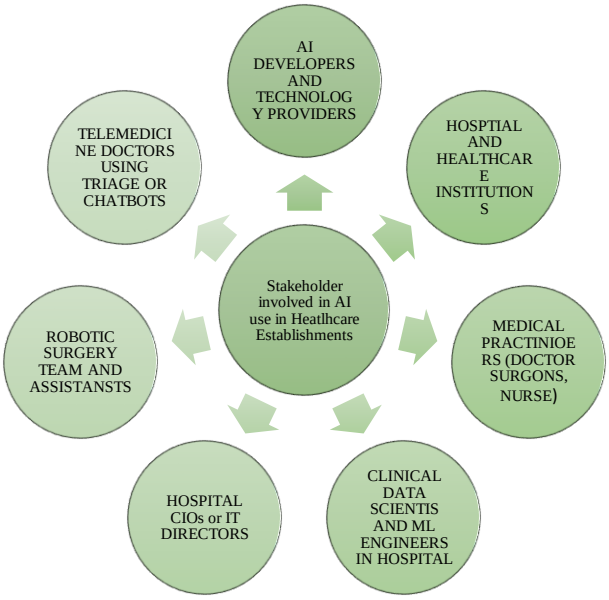
AI DEVELOPERS AND TECHNOLOG Y PROVIDERS
HOSPTIAL AND HEALTHCAR E INSTITUTION S
MEDICAL PRACTINIOE RS (DOCTOR SURGONS, NURSE)
CLINICAL DATA SCIENTIS AND ML ENGINEERS IN HOSPITAL
HOSPITAL CIOs or IT DIRECTORS
ROBOTIC SURGERY TEAM AND ASSISTANSTS
TELEMEDICI NE DOCTORS USING TRIAGE OR CHATBOTS
Stakeholder involved in AI use in Heatlhcare Establishments

Figure 8- Stakeholder involved use of AI in healthcare

2. STATEMENT OF PROBLEM

The rapid integration of artificial intelligence technologies into the healthcare systems. Ranging from robot assisted surgeries and autonomous diagnostic tools to algorithm decision support, Systems has introduced a transformative efficiencies and capabilities. These technologies promise to improve the patient outcome, faster diagnostic and more cost-effective health care delivery towards the. Ride to health for everyone. Yet this technology revolution has developed at peace that far outstripped the evolution of cross bonding legal and regulated frameworks. In particular, the question of liability for harm caused by the use of artificial intelligence system in health care remains unresolved.

Where the traditional liability in healthcare has been allocated under doctrines such as negligence, product liability and the consumer protection law these frameworks are grounded in a human centric model of responsibility. They assume the identifiable actors who exercise intent, fault or control, however. The emergence of more autonomous and opaque nature of artificial intelligence often described as the black box problem Challenge these assumptions.

When application of artificial intelligence system produces in Anonymous diagnosis or malfunction during surgical or non-surgical determining the liability becomes complex. Is it the clinical who relied on the AI output, the hospital that deploy the technology, the developer who designed the algorithms or the vendor who supplied the tool? The existing doctrines and regulations do not provide a clear answer to this issue. The problem is acute in healthcare, where the stakes are uniquely high, the error may Cause irreversible harm to the Patients

especially the Vulnerable and liability allocation directly effects trust in medical system. The central problem of this research addresses the legal uncertainty surrounding the liability in artificial intelligence driven health care establishment. The current liability regimes recorded not sufficient to accommodate the complexities of artificial intelligence systems because it only includes the software, not the artificial intelligence or artificial intelligence agents or agentic artificial intelligence in attribution of fault and proof of caution. The absence of AI specific liability regulations creates hesitations among the stakeholders to adopt the AI for better healthcare. For this issue systematic legal inquiry Which include the doctrinal and empirical study is necessary to develop a liability framework which ensures legal certainty, protects the right of the patients and supports the responsible development and adoption of artificial intelligence in healthcare establishments.

3. LITERATURE REVIEW

The literature review around the Healthcare and medical and Liability was conducted with quantitative and Qualitative methods in two distinct phases during the initial phase a compreshive examination of healthcare and Artificial intelligence liability was undertaken to gain a comprehensive understanding of the overarching concept existed in current literature. In subsequent phase, A detailed analysis of selected paper was conducted in II PHASES, to get the clarity of the current state of research and to find out the gaps under the literature. In Phase I literature, quotative approach has been used and Bibliometric analysis method adopted to review the data and whereas in phase II a review of selected and most relevant articles is completed, conducting a literature review through esteemed databased such as SCOPUS and WOS hold pivotal importance in academic research (See Figure 9) *Page MJ, et al. BMJ 2021*. These platforms provide vast and well-selected databases of academic publications, ensuring the reliability and relation with real science of the results obtained. From these resources, researchers identify existing lack of knowledge, refine their research directions and contextualise the significance of their own contributions among those within the broader academic community. A heavily debated review process would not only lead to having more reliable le research, but it also allows for well-informed, context-sensitive project submissions and papers and therefore systematically guided knowledge progress evidenced based.. For the final selection of Article or research paper the literature was manually refined full text available and to title consisting the term “Artificial Intelligence “and Liability and (Healthcare OR Medical OR Medicine)

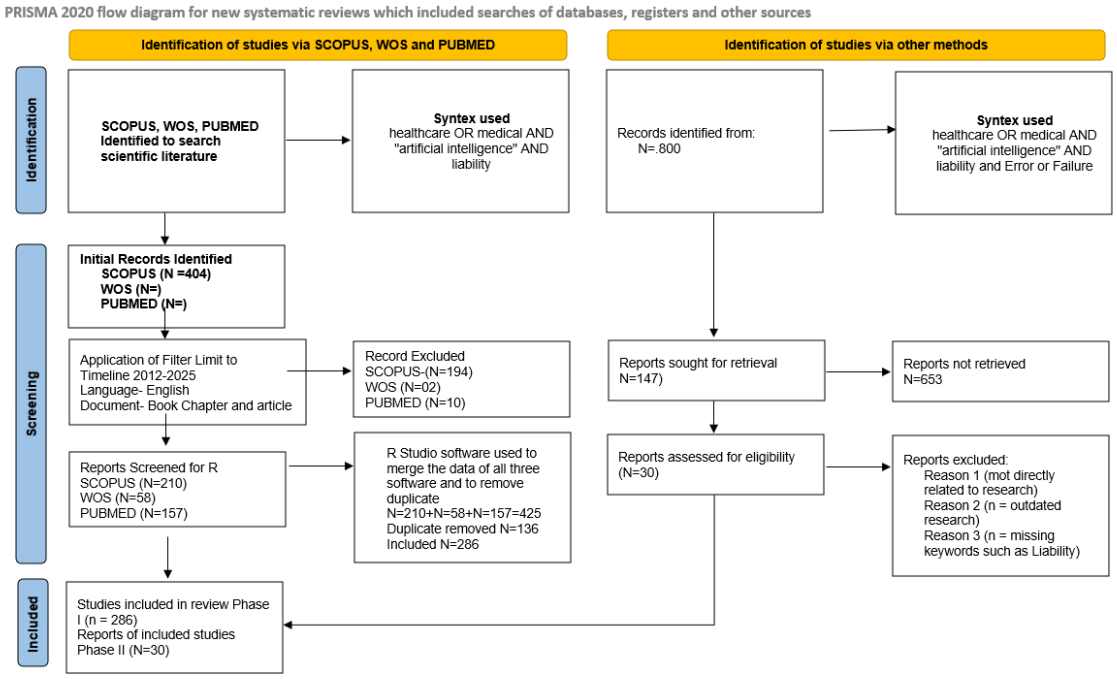
PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources
Identification of studies via SCOPUS, WOS and PUBMED
Identification of studies via other methods
Identification
SCOPUS, WOS, PUBMED Identified to search scientific literature
Syntex used healthcare OR medical AND "artificial intelligence" AND liability
Records identified from: N=.800
Syntex used healthcare OR medical AND "artificial intelligence" AND liability and Error or Failure
Screening
Initial Records Identified SCOPUS (N =404) WOS (N=) PUBMED (N=)
Application of Filter Limit to Timeline 2012-2025 Language- English Document- Book Chapter and article
Record Excluded SCOPUS-(N=194) WOS (N=02) PUBMED (N=10)
Reports sought for retrieval N=147)
Reports not retrieved N=653
Reports Screened for R SCOPUS (N=210) WOS (N=58) PUBMED (N=157)
R Studio software used to merge the data of all three software and to remove duplicate N=210+N=58+N=157=425 Duplicate removed N=136 Included N=286
Reports assessed for eligibility (N=30)
Reports excluded: Reason 1 (mot directly related to research) Reason 2 (n = outdated research) Reason 3 (n = missing keywords such as Liability)
Included
Studies included in review Phase I (n = 286) Reports of included studies Phase II (N=30)

Figure 9- PRISMA for Literature review

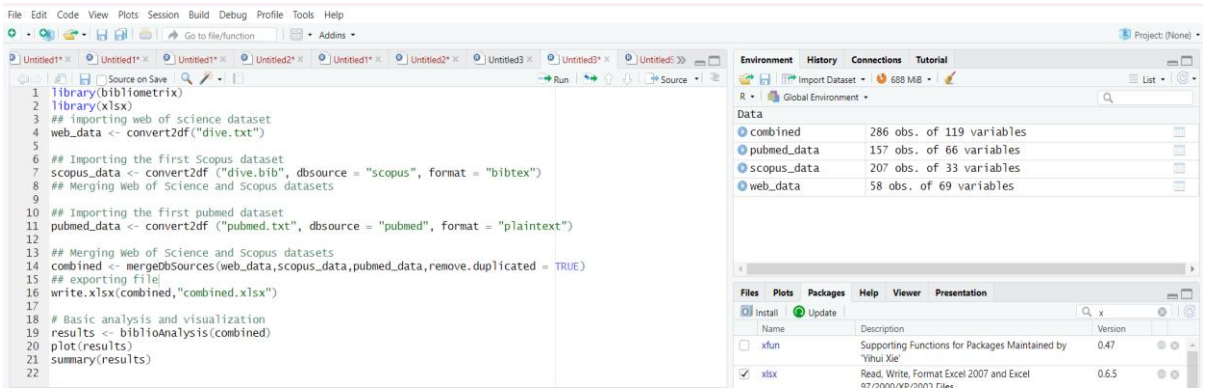
library(bibliometrix)
library(xlsx)
importing web of science dataset
web_data <- convert2df("dive.txt")
Importing the first Scopus dataset
scopus_data <- convert2df ("dive.bib", dbsource = "scopus", format = "bibtex")
Merging Web of Science and Scopus datasets
Importing the first pubmed dataset
pubmed_data <- convert2df ("pubmed.txt", dbsource = "pubmed", format = "plaintext")
Merging Web of Science and Scopus datasets
combined <- mergeDbSources(web_data,scopus_data,pubmed_data,remove.duplicated = TRUE)
exporting file
write.xlsx(combined,"combined.xlsx")
# Basic analysis and visualization
results <- biblioAnalysis(combined)
plot(results)
summary(results)
Data
combined 286 obs. of 119 variables
pubmed_data 157 obs. of 66 variables
scopus_data 207 obs. of 33 variables
web_data 58 obs. of 69 variables

Figure 10- Application of R for Screening

3.1 Phase I Analysis

Bibliometric and thematic analysis of scientific documents published in the field of Artificial Intelligence (AI), healthcare and legal liability (2012-2025) see Table 1 an interdisciplinary field in expansion and maturation. As shown in Figure 11 and table 2 (Annual Scientific Production), the scientific product increased dramatically after 2019 and reached its peak (83) in 2024; the average growth rate remained high (31.16%). This speaks to the heightened global attention to AI-enabled healthcare governance. Figure 14 representing the (Countrywide Scientific Production), where it is clear that the US (137) and China (50) are the major contributors in this area, with countries in Africa, Latin America and certain areas of Asia being underrepresented and pointing to a regional research gap in discourse about regulation and ethical issues. The Trend Topics chart (Figure 13) highlights recent research exploring controversial issues surrounding informed medical decision making, the

role of healthcare workers in an era of advanced technologies, and questions of responsibility and patient autonomy. Terms frequently encountered in recent publications included "ethics", "choice", and "artificial intelligence", especially after 2021. As represented in Thematic Map (Figure 12), studies fall into four categories: "Motor Themes" dealing with issues like women's healthcare and liability considerations are well established and core concerns; "Basic Themes" involving matters like clinical judgement and legislation over AI are foundational but less developed areas of inquiry; "Niche Themes" such as AI ethics and liability questions raised in China focus on specialized topics with less connection to mainstream dialogue; and "Emerging or Declining Themes" like the impact of big data on complex medical scenarios and its legal implications remain on the edges of discussion for digital health rights remain peripheral. While collaboration across borders on publications related to legal matters remains low, indicated by the small percentage involving international co-authorship despite prolific output, the need for integration of ethical and legal considerations into applicable solutions is clear. Fragmentation plagues practical implementation of frameworks addressing these vital issues, especially in less developed areas. More empirical work engaging with real world complexities could help address this through diverse types of research consolidating dispersed efforts and bridging geographical and topical divides to better serve all contexts Research

While the finding present in Table 1 evidence suggests progress, pressing issues require immediate attention in the multifaceted sphere of artificial intelligence oversight concerning healthcare. Primarily, cross-national examinations of traditional liability model compared to emerging economic state's management of AI implementation, liability criteria, and patient data protections are conspicuously absent. Additionally, minimal studies thoroughly explore how patients from diverse linguistic or rural backgrounds genuinely comprehend and consent to algorithm-guided clinical choices, despite terms like "informed consent," "medical liability," and "technology ethics" permeating discourse See figure 13. The thematic framework shown in (figure 12) positions "responsibility," "regulation," and "values" on the periphery, highlighting the disjointed and formative nature of enforcement across the domain. Overall, building upon beginnings but addressing critical gaps with heightened cross-disciplinary collaboration is imperative moving forward. because many AI systems also include the feature of black boxes the legal responsibility in particular with regard to the respective roles of software developers vs. doctor decision making are still insufficiently developed. In addition, policy implementation review, interdisciplinary regulatory models, and AI auditing mechanisms should be the priority focus in the Future scholarship, and empirical field work inside the hospital to capture legal awareness among stakeholders.

Table 1: Main Information of Data

Description	Results
MAIN INFORMATION ABOUT DATA	
Timespan	2012:2025
Sources (Journals, Books, etc)	234
Documents	286
Annual Growth Rate %	31.16
Document Average Age	2.29
Average citations per doc	15.77
AUTHORS	
Authors	995
Authors of single-authored docs	61
AUTHORS COLLABORATION	
Single-authored docs	63
Co-Authors per Doc	3.81
International co-authorships %	9.441
DOCUMENT TYPES	
article	162
article article	2
article; book chapter	1
article; early access	1
article; retracted publication	1
book chapter	48
editorial	2
journal article	13
journal article;research support, non-u.s. gov't	2
journal article;research support, non-u.s. gov't;review	1
journal article;review	28
journal article;scoping review	4
journal article;systematic review	2
letter	3
proceedings paper	2
published erratum	1
review	13

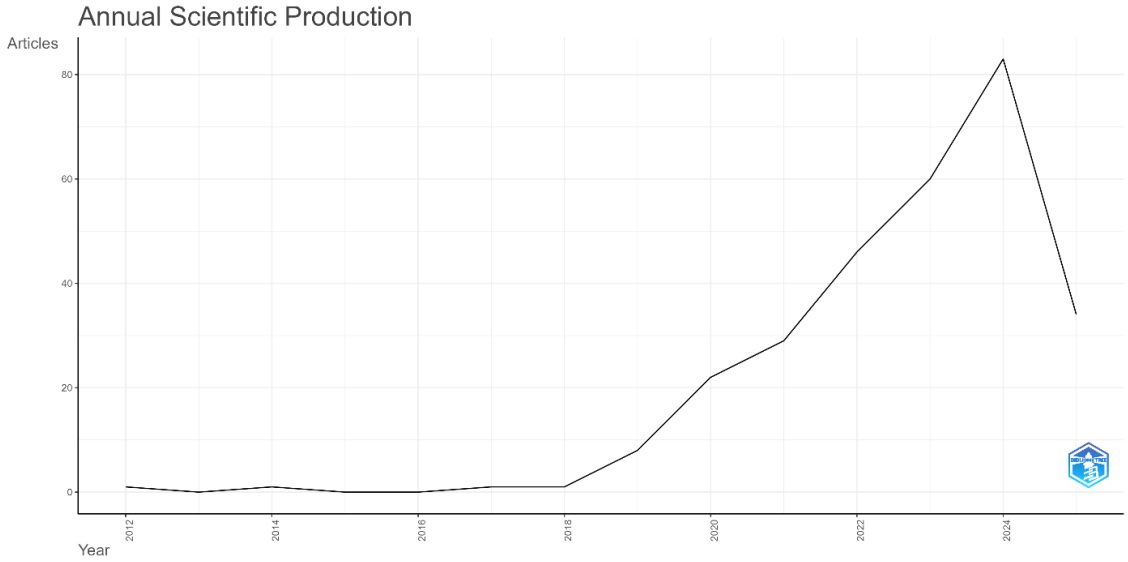

Figure 11- Annual scientific production

Table 2: Annual scientific production year wise

Year	Articles
2012	1
2013	0
2014	1
2015	0
2016	0
2017	1
2018	1
2019	8
2020	22
2021	29
2022	46
2023	60
2024	83
2025	34

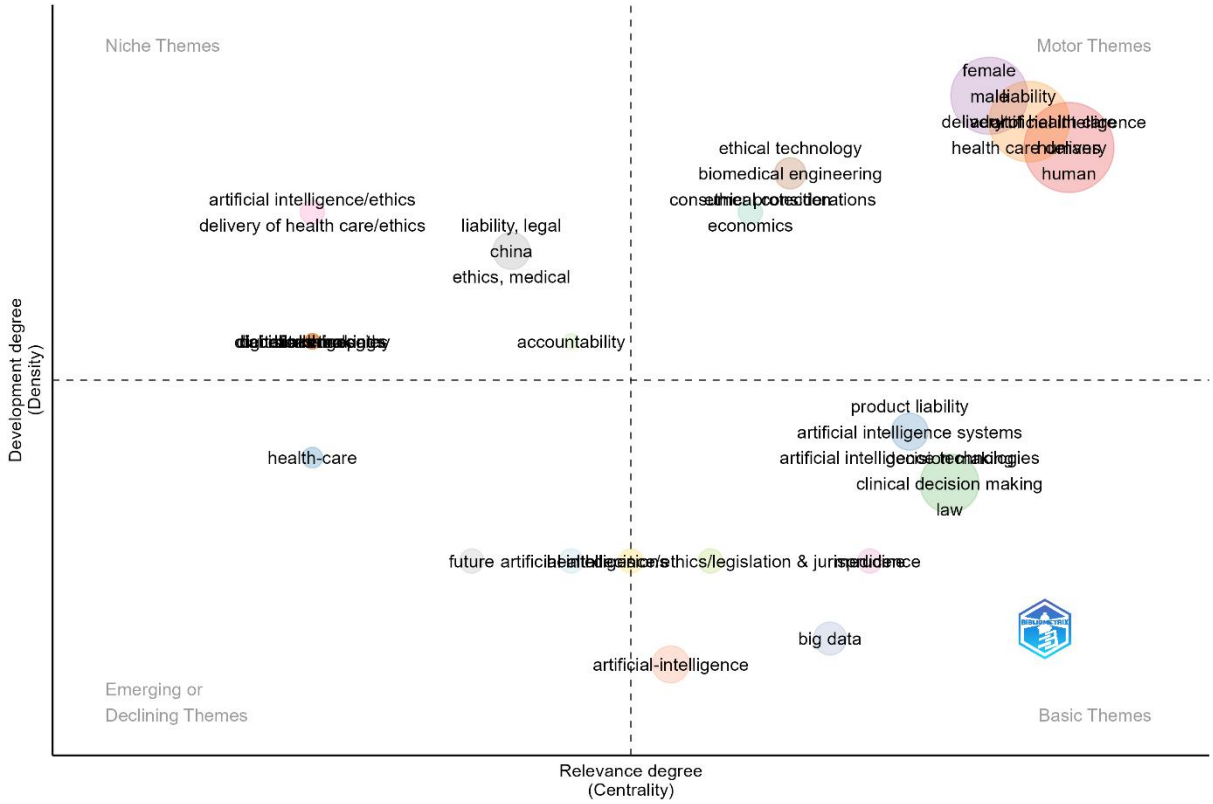

Figure 12: Thematic map of theme around Artificial application in healthcare

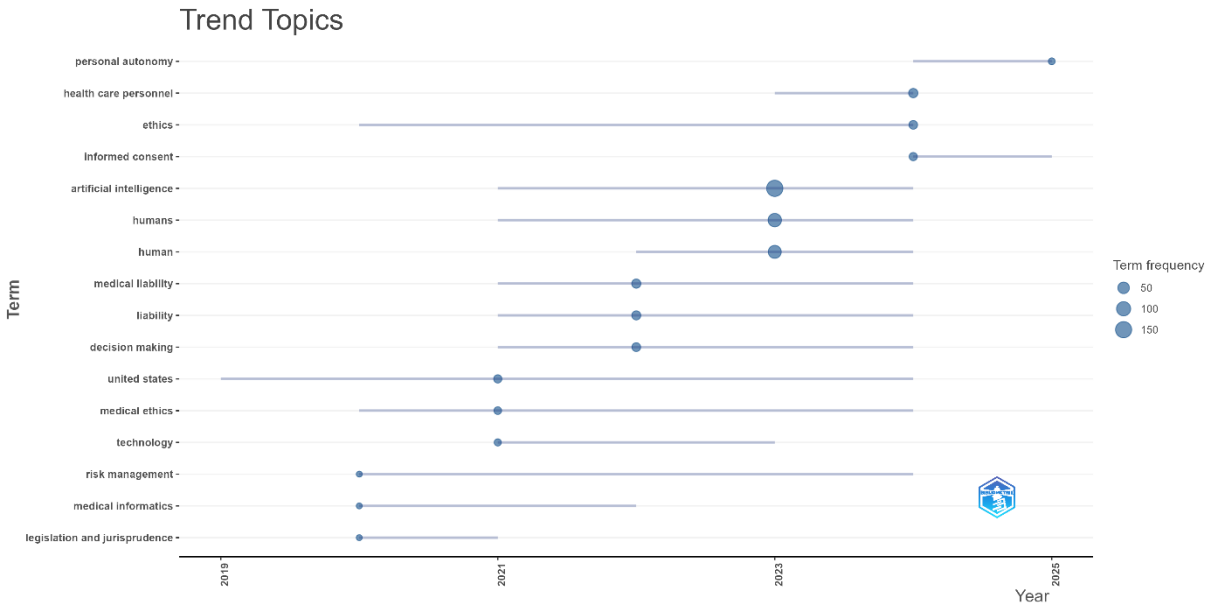

Figure 13: Trending topic around the AI and Healthcare

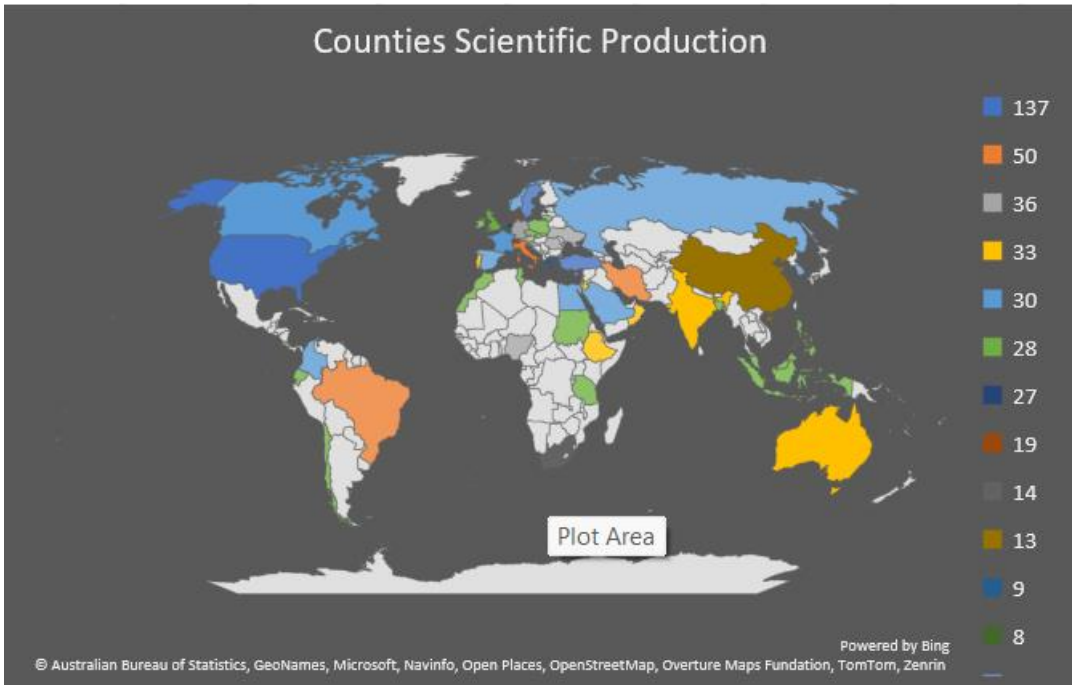

Figure 14- Countries scientific production around AI application in healthcare and Liability

3.2 Phase II Analysis

Table 3: Systematic literature review of Selected paper

S.no	Research paper	Objective	Findings	Research Gap	Future Research
1.	The proposed EU Directives for AI liability leaves worrying gaps likely to impact medical AI *Duffourc, M. N., & Gerke, S. (2023)*	The paper aims to address liability for AI-caused harm through proposed Directives in the EU. It seeks to identify and fill potential liability gaps for black-box medical AI systems The research highlights the need for uniform liability rules to enhance trust in AI It examines the implications of existing liability frameworks on manufacturers and	The proposed Product Liability Directive (PLD) and AI Liability Directive (AILD) aim to address liability for AI-caused harm in the EU These Directives fail to fully achieve clarity and uniformity for injuries caused by black-box medical AI systems Potential liability gaps exist,	The proposed EU Directives may not provide a clear path to liability for injuries caused by black-box medical AI systems. Patients may struggle to sue manufacturers or healthcare providers under existing liability laws The Directives fail to address potential liability gaps, hindering the use	Future research should address liability gaps for injuries caused by black-box medical AI systems under existing EU laws Investigating the implications of non-autonomous AI's predictions on patient safety is crucial Exploring the potential for harmonized liability measures across EU Member

		healthcare providers . The objectives include improving conditions for the development of medical AI systems	hindering victims' ability to sue manufacturers or healthcare providers for AI-related injuries The absence of clear liability paths may discourage manufacturers and healthcare providers from utilizing beneficial black-box medical AI systems The European Commission (EC) aims to enhance public trust in AI through harmonized liability measures, which the current proposals do not fulfill	of beneficial black-box medical AI systems There is uncertainty regarding liability risks for manufacturers and healthcare providers due to these gaps The lack of uniform liability rules may lead to distorted competition among businesses in different EU Member States	States is necessary to enhance legal certainty Research should focus on the development of interpretable AI models to mitigate liability risks Assessing the impact of proposed Directives on manufacturers' and healthcare providers' willingness to adopt AI technologies is essential
2.	Understanding Artificial Intelligence Along with Legal and Ethical Issues Clinical. *FN, Sayın S. (2024)*	The paper investigates fundamental ethical and legal considerations regarding AI technologies in healthcare services It aims to address the risks associated with unmonitored AI utilization affecting	AI technologies in healthcare present both opportunities for advancements and challenges related to ethical and legal concerns Transparency and accountability are essential for fostering trust in	There are significant gaps in understanding the ethical and legal implications of AI technologies in healthcare The necessity for new laws specific to AI in healthcare remains unclear	Future research should focus on developing ethical AI frameworks tailored to healthcare applications Investigating the impact of AI on patient privacy and data protection is

		patients and healthcare professionals The research emphasizes the need for robust legal and ethical frameworks to manage AI technologies effectively It seeks to clarify the responsibilities of AI developers and healthcare professionals in mitigating risks	AI technologies among stakeholders Ethical guidelines and monitoring are necessary to mitigate unforeseen outcomes in AI implementation AI companies must educate society about potential risks associated with their technologies The training data for AI algorithms must fairly represent all patient demographics to avoid biases No financial support was received from pharmaceutical companies, ensuring unbiased research evaluation The unmonitored use of AI can lead to adverse outcomes for patients and healthcare professionals	Existing regulations are often inadequate for addressing AI-induced damages The representativeness of training data in AI systems is a critical concern The impact of AI on physicians' skills and decision-making processes requires further investigation . Clarifying accountability for AI decisions that cannot be fully explained is essential The ongoing debates about discrimination in AI applications highlight a need for more research The abstract emphasizes the need for better regulations to prevent abuses in AI utilization	crucial Addressing biases in AI training data to improve accuracy across diverse populations is necessary Exploring the transparency and explainability of AI systems can enhance trust and accountability Research should evaluate the legal implications of AI technologies in healthcare settings Understanding the socio-technical dynamics among stakeholders in AI development is essential

			.		
3.	The Price of Autonomy: Liability Standards for Complementary and Substitutive Medical Robotics And Artificial Intelligence Pasquale III, F. A. (2022).	The paper aims to develop a binary approach for structuring policy discussions on liability for AI and robotics in medical contexts It seeks to assess responsibility for preventable adverse outcomes involving AI and robotics in healthcare The research discusses the implications of substitutive versus complementary automation in tort law and labor policy It emphasizes the need for accountability from vendors of AI systems when they replace skilled professionals The paper advocates for a mixed negligence-strict liability regime to address technological advancements in medicine .	The paper proposes a binary approach to liability for AI and robotics in medical contexts, distinguishing between substitutive and complementary automation It argues that vendors of substitutive AI should bear responsibility for errors, shifting liability from medical professionals The doctrine of strict liability applies when technology is defective and unreasonably dangerous, particularly in medical applications The paper emphasizes the need for clear standards of responsibility to ensure	The paper highlights a lack of diversity in genomics research, particularly in DNA databases, affecting the applicability of findings There is insufficient exploration of the transition from human assistance to full automation in medical contexts The paper notes that scientific evidence is often difficult for laypeople to interpret, indicating a gap in public understanding The role of manufacturers in ensuring safety and transparency of robotic devices remains underexplored The impact of hold harmless clauses on patient rights and safety is not adequately	Future research could explore the balance between substitutive and complementary automation in medical contexts . Investigating the impact of liability frameworks on the development of autonomous systems is essential The role of professionals in mediating technology and patient care warrants further examination . Research should assess the effectiveness of AI in enhancing patient safety and outcomes Understanding the implications of strict liability on AI vendors and their accountability is crucial

			accountability in AI failures It highlights the importance of competent human intervention in mitigating risks associated with advanced technology in medicine	addressed	
4.	The impact of digital health technologies on moral responsibility: a scoping review *Meier et al., (2024)*	The study investigates how responsibility is interpreted in digital health technologies, including AI and telemonitoring. It aims to explore the perceived moral responsibilities of various stakeholders The research seeks to address uncertainties that may impact healthcare quality and safety It recommends further study on collective responsibility and the role of virtue in digital health The paper categorizes included articles using a theoretical framework of responsibility aspects	The study identified 34 articles focusing on moral responsibility in digital health technologies, revealing a significant theoretical emphasis in the literature Key findings include the emergence of a 'responsibility gap' in AI-generated outcomes, complicating accountability The literature indicates that m-Health technologies can enhance patient accountability for their health	The literature lacks discussions on collective responsibility frameworks in digital health technologies There is limited empirical research on accountability in AI-generated outcomes Most studies originate from European countries, indicating a geographical research gap The review did not differentiate between empirical and theoretical interpretations of responsibility Further research is needed on the	Further ethical and legal research is needed on the responsibilities of autonomous technologies in digital health contexts Exploration of whether artificial entities can be responsible actors is essential Incorporating collective responsibility into individualized frameworks is suggested to address accountability gaps Research should focus on the perceived responsibilities of various actors using real-world

			The review highlights the need for further research on collective responsibility and the role of virtue in digital health The analysis found limited discussion on the appropriateness of accountability attributions in the reviewed literature	perceived responsibilities of various actors in real-world scenarios	examples Emphasis on virtue responsibility and its role in accountability is necessary Identifying all stakeholders in the collective responsibility for digital health technology use is important The study highlights a need for further investigation into the accountability of AI-generated outcomes
5.	The difficult role of Artificial Intelligence in Medical Liability: to err is not only human *Tozzo et al., (2021)*	The paper aims to explore the impact of AI technologies on medical assistance and decision-making processes for clinicians It investigates the legal and ethical implications of AI's role in the doctor-patient relationship [research discusses the	The paper discusses the rapid integration of AI technologies in medical assistance, enhancing decision-making for clinicians It highlights the complexities of liability attribution in cases involving AI systems The introduction of AI in healthcare raises	The paper highlights the need for a dedicated legal framework for AI in healthcare, indicating a gap in current regulations There is a lack of consensus on whether new laws are necessary for AI's role in healthcare, suggesting differing expert opinions The ethical	Future research could explore the legal implications of AI in healthcare, particularly regarding liability in compensation lawsuits and criminal cases Investigating the ethical considerations surrounding AI's role in the doctor-patient relationship is essential for future studies There is a need to

			significant legal and ethical considerations There is a debate on whether new legal frameworks for AI in healthcare are necessary	implications of AI in the doctor-patient relationship remain underexplored, presenting a significant research opportunity	establish a dedicated legal framework for AI technologies in healthcare, which warrants further exploration
6.	The Criminal Liability of Artificial Intelligence Entities Jafar Ali Hammouri1, Hammouri et al., (2024)	The research aims to explore legal challenges posed by AI regarding criminal liability It seeks to identify appropriate legal frameworks for assigning responsibility The study examines different models of liability related to AI actions It assesses the legal implications of AI's actions in criminal contexts The research proposes legislative solutions to address the identified challenges It aims to model the development of criminal legislation for AI-related issues	The research identifies significant challenges to traditional legal systems regarding AI and criminal liability due to AI's autonomous capabilities It emphasizes the need for new legislation that clearly defines criminal responsibility for AI entities, manufacturers, and users The study proposes that legal frameworks must adapt to technological changes and align with ethical standards and human rights protections	The paper highlights the inadequacy of existing legal frameworks to address AI-related crimes, indicating a gap in legislative development There is a need for clear definitions of criminal responsibility for AI entities, manufacturers, and users The research identifies a lack of comprehensive legal models that adapt traditional principles to AI's autonomous nature The study suggests that current laws do not sufficiently cover the complexities introduced by AI's	Future research should focus on developing new laws that clarify criminal responsibility for AI entities and their users Investigating the adaptation of traditional legal principles to address AI's autonomous actions is essential Analyzing the strengths and weaknesses of current legal frameworks regarding AI and criminal liability is necessary Exploring the implications of AI's decision-making capabilities on accountability and responsibility is

			It highlights the importance of global cooperation in establishing consistent legal standards for responsible AI use The findings suggest that modernizing criminal law is essential to balance innovation with justice and security in an AI-driven world	decision-making capabilities There is an absence of proposed solutions for enhancing legal frameworks to manage AI's growing autonomy	crucial for legal evolution Research should also assess the ethical integration of AI technologies within existing legal systems
7.	When Does Physician Use of AI Increase Liability? *Tobia et al., (2021)*	The research aims to explore the liability implications for physicians using AI in medical recommendations It investigates under what circumstances jurors would hold physicians liable for AI-assisted decisions The study provides experimental evidence on how standard care and AI recommendations affect liability perceptions It assesses the impact of AI recommendations on	The study indicates that AI recommendations can reduce physicians' liability when accepted rather than rejected Participants evaluated liability based on whether the physician followed standard or AI recommendations The findings suggest lay jurors consider both AI and standard care in their judgments The results extend	The study does not fully model real jury trial procedures, particularly regarding expert testimony on AI precision medicine There is limited exploration of laypeople's algorithm aversion in medical contexts beyond the study's fin The paper does not address potential biases in jurors' judgments regarding AI recommendations	Future research could explore the impact of AI recommendations on juror perceptions of liability in medical malpractice cases Investigating the effects of algorithm aversion among laypeople in medical contexts may provide valuable insights Further studies could assess how nonlegal factors influence physicians'

		physicians' legal risks in precision medicine The research seeks to inform physicians on reducing liability through adherence to AI advice	to medical negligence standards, indicating common care influences lay judgments A total of 2,060 participants completed the study, with exclusions for comprehension checks The study's preregistered analyses confirmed the robustness of the findings	in diverse demographic groups The implications of AI's evolving role in personalized medicine and its legal ramifications require further investigation	decisions regarding AI recommendations Research could examine the long-term implications of AI usage in standard versus nonstandard care scenarios Exploring the role of expert testimony in jury trials involving AI recommendations could enhance understanding of juror decision-making
8.	When AI Is Wrong: Addressing Liability Challenges in Women's Healthcare Marotta, A. (2022).	The study aims to analyze the role of AI in women's healthcare and its liability implications from AI mistakes It seeks to evaluate the potential consequences of AI decision-making processes and affected parties The research intends to develop a framework for algorithmic auditing to ensure fair AI practices It emphasizes	he study highlights the critical role of AI in women's healthcare and its liability implications due to potential errors Bias in AI datasets can significantly affect decision-making processes in healthcare, necessitating careful evaluation The research	The paper highlights the need for more investment in addressing AI bias, including algorithm fairness and governance There is a lack of infrastructure in healthcare organizations for training AI algorithms consistently across diverse patient groups	Future research should focus on addressing AI bias, including algorithm fairness and governance issues Investigating the implications of AI in women's healthcare is essential for improving outcomes Developing frameworks for algorithmic auditing to ensure

		understanding and recognizing biases in AI algorithms to improve healthcare outcomes The study also aims to address complex concerns of AI bias, including fairness and governance	emphasizes the importance of auditing methods to enhance transparency and identify issues in AI systems The Forward-Backward (FB) analysis method is effective for understanding AI's impact and addressing potential failures Human interaction with AI systems is crucial for mitigating risks and ensuring accurate medical decisions .	The study indicates that AI systems may not reliably function in novel medical conditions, raising concerns about their validity The paper acknowledges the preliminary nature of its findings, suggesting further empirical research is necessary It points out the challenge of ensuring objectivity in auditing AI systems for bias, indicating a gap in effective auditing practices	fair AI practices is necessary Exploring the legal responsibilities of stakeholders in AI-driven decision-making is crucial Understanding the complexities of Clinical Decision Support Systems (CDSS) and their implications for medical liability warrants further study
9.	Liability of Health Professionals Using Sensors, Telemedicine and Artificial Intelligence for Remote Healthcare Geny et al., (2024).	The paper aims to analyze the liability of health professionals using sensors and AI tools in remote healthcare It discusses different liability regimes: contract-based, breach of duty, fault-based, and the approach related to the good itself The research also explores future	The study evaluated 157 publications, ultimately including 81 in the review related to AI and sensors in healthcare AI and sensors can enhance patient care pathways and public health outcomes, especially during	The paper highlights a lack of clarity around accountability in AI and sensor use in healthcare There is insufficient documentation and code sharing in AI research studies Generalizability of AI findings across diverse populations remains a core	Future research should focus on the validation of AI technologies in healthcare, especially during public health crises like COVID-19 There is a need for clearer definitions of liability concerning AI and sensor use in healthcare New regulations

		challenges and opportunities in the use of sensors and AI in medicine [	crises like COVID-19 The paper discusses the importance of liability definitions in the context of AI use in healthcare Different liability regimes are analyzed, including contract-based and fault-based approaches . The findings indicate that while AI has potential, there is reluctance among doctors and patients to adopt it due to liability concerns .	issue The paper identifies a need for clearer definitions of liability in AI-assisted medical decisions Future challenges and opportunities in the use of sensors and AI in medicine are not fully explored .	regarding sensor devices and AI liability are anticipated as their autonomy increases The generalizability of AI findings across diverse populations requires further investigation Ethical, technical, and public health aspects of liability related to AI and sensors need more exploration
10.	Regulatory sandboxes in the AI Act: reconciling innovation and safety? Thomas et al., (2023).	The paper explores the regulatory sandbox regime under the EU's draft AI Act for testing AI-based skin cancer detection system It aims to suggest a targeted legal basis for the sandbox regime inspired by conventional testing	The paper explores the regulatory sandbox regime under the EU's draft AI Act for testing AI-based skin cancer detection systems It suggests a targeted legal basis for the	The paper identifies a regulatory gap in the application of AI systems in medical diagnostics, particularly regarding telediagnosis procedures There is a lack of	Future research could explore the implementation of a regulatory sandbox for AI-based medical systems to enhance patient safety and innovation Investigating the effectiveness of clinical

		mechanisms The research investigates balancing innovation and safety in medical AI systems It emphasizes the need for real-world testing of AI systems in medical contexts The study addresses legal implications and regulatory challenges associated with AI technologies .	sandbox regime inspired by conventional testing mechanisms like clinical investigations The findings highlight the need for real-world testing of AI systems to ensure safety and efficacy Regulatory sandboxes can help legislators understand the adequacy of existing laws in the context of new technologies The paper emphasizes balancing innovation and safety through flexible regulatory approaches	specific procedures in the Doctors Act 1998 for testing new technologies in medical practice The need for a clearer legal framework for AI-based decision support in medical settings is highlighted The paper suggests that further exploration is needed on the extent of doctors' obligations when using AI systems The abstract indicates a gap in understanding how regulatory sandboxes can effectively test AI-based medical systems .	investigations as a flexible testing regime for medical devices is suggested Further examination of the legal implications of AI in telediagnosis is necessary, particularly regarding doctor-patient interactions Research could focus on developing experimental clauses that allow deviations from existing laws for innovative testing
11.	The Autonomous AI Physician: Medical Ethics and Legal Liability Duffourc et al., (2023).	The paper aims to explore ethical parameters for the Autonomous AI Physician's practice of medicine, particularly in pathology It identifies ethical and	The Autonomous AI Physician can perform medical practices like diagnosis and therapeutic decision-making, raising questions	The paper does not address the specific legal frameworks needed for AI's medical practice and liability assignment There is a lack of	Future research should explore the ethical parameters for the Autonomous AI Physician's practice in medicine, particularly in

		legal issues arising from AI's medical practice, including safety, reliability, and accountability esearch discusses the application of existing legal and regulatory frameworks to govern the Autonomous AI Physician It emphasizes the obligation of stakeholders to ensure safe and responsible AI implementation in healthcare	about its status as a medical practitioner Ethical parameters for the Autonomous AI Physician's practice include safety, reliability, transparency, fairness, and accountability Various legal and regulatory regimes may apply to govern the Autonomous AI Physician's operations Medical malpractice standards may evolve as attorneys utilize methods like "nearest neighbor" and "AI cross-testing" for evaluating AI decisions Health Information Counselors (HICs) could bridge the gap between patients and AI, requiring structural changes	clarity on how to ensure AI's clinical reliability and safety The implications of the "black-box" problem on accountability and oversight are not fully explored Ethical considerations regarding patient consent for data usage in AI training are inadequately discussed The potential biases in AI training data and their impact on decision-making require further investigation	pathology Investigating the legal frameworks governing AI-caused harm in healthcare is essential for addressing liability issues Research is needed on the reliability and safety of AI decisions in clinical settings to ensure patient safety The unpredictability of AI algorithms necessitates further study on their implications for medical decision-making Examining the integration of no-fault compensation systems for AI-related medical injuries could enhance recovery access

			for effective implementation The GDPR provides enhanced data protection for AI-related personal data, necessitating compliance in clinical settings Stakeholders must ensure the safe and responsible implementation of AI in healthcare through regulatory and legal mechanisms		
12.	Presenting artificial intelligence, deep learning, and machine learning studies to clinicians and healthcare stakeholders: an introductory reference with a guideline and a Clinical AI Research (CAIR) checklist proposal *Olczak et al (2021).*	The paper aims to evaluate AI research in medicine, particularly in orthopedics, focusing on commonly encountered tasks It proposes guidelines for reporting medical AI research to clinicians, including a Clinical Artificial Intelligence Research (CAIR) checklist The authors envision a broader consensus process for reporting and understanding AI studies' outcomes	The paper proposes the CAIR checklist to improve reporting of AI and ML research for healthcare stakeholder It emphasizes the need for clinicians to understand AI developments to benefit from them Ethical considerations in AI research are crucial, as low-quality studies can	The paper does not cover all aspects of AI and ML in medicine or orthopedics, indicating a significant research gap The selection of tasks in medical AI studies may evolve, suggesting a need for ongoing research in this area There is a lack of comprehensive guidelines for	Future research should focus on improving AI models' interpretability and safety in medical applications Development of comprehensive reporting guidelines for AI studies is essential Exploration of performance measures suitable for AI models in healthcare is

		The goal is to enhance clinicians' understanding of AI developments to improve patient care The research emphasizes the importance of transparency and interpretability in AI for clinical applications	hinder meaningful outcomes The paper highlights the importance of transparency and interpretability in AI for clinical applications It discusses the evolving nature of tasks in medical AI, particularly in orthopedics The authors advocate for standardized performance measures to accurately assess AI research outcomes	reporting AI and ML research, highlighting a gap in standardized practices	needed The evolving familiarity of clinicians with AI necessitates ongoing research in orthopedic applications Addressing biases in AI studies through enhanced reporting checklists is crucial
13.	Potential Liability for Physicians Using Artificial Intelligence Price, et al (2019)	The paper aims to explore the integration of AI in medical practice, particularly in clinical decision-making It discusses the potential for AI to personalize patient care The research examines the implications of AI recommendations on the standard of care and physician liability It highlights	The paper discusses the integration of AI in medical practice, highlighting its potential to support clinical decisions and personalize care It emphasizes the importance of using AI as a confirmatory tool to mitigate liability risks for	Not found in the paper	Future research could explore how AI recommendations may shift the legal standard of care over time Investigating the complexities of physician liability in relation to medical AI is essential Research should focus on the integration of AI

		the challenges posed by current laws that may limit the adoption of AI in medicine The study also addresses the accuracy and reliability of AI in medical recommendations	physicians The analysis indicates that current tort law may treat AI recommendations differently, affecting physician liability Physicians may face liability for rejecting correct AI recommendations, complicating their decision-making process The paper warns that the threat of liability may lead physicians to undervalue AI's potential benefits		into clinical practice and its implications for patient care Understanding the potential for AI to personalize treatment recommendations warrants further investigation
14.	Medical malpractice liability in large language model artificial intelligence: legal review and policy recommendations *Shumway, D. O., & Hartman, H. J. (2024).*	The paper aims to discuss legal vulnerabilities for clinicians using LLM AI in medical decision-making It reviews past case law related to third-party medical guidance The authors propose proactive policy recommendations for algorithmic	he paper highlights the potential of generative LLM AI to revolutionize healthcare practices significantly Concerns regarding liability for adverse outcomes from LLM AI-influenced	The paper identifies a lack of comprehensive federal regulations addressing liability for LLM AI-influenced medical decisions There is insufficient precedent in U.S. case law regarding medical malpractice related to LLM AI	Future research should focus on the legal implications of LLM AI in clinical settings, particularly regarding liability for medical decisions Investigating the effectiveness of rigorous validation and testing protocols for AI tools before clinical

		transparency and validation testing The research highlights the need for clarity on malpractice liability concerning AI-influenced decisions It emphasizes the potential of generative LLM AI to revolutionize healthcare practices	decisions are emphasized The authors found no adjudicated cases of medical malpractice involving LLM AI in the U.S. Recommendations include rigorous validation and testing of AI tools before clinical deployment	The need for rigorous validation and testing of AI tools before clinical deployment is emphasized The paper suggests that algorithmic transparency and independent validation are necessary but currently lacking The potential for state-level tort reform to address liability issues remains unexplored	deployment is essential Exploring the need for algorithmic transparency and peer-reviewed data in LLM AI applications is crucial Examining the potential for tort reform to address liability issues related to AI-generated medical guidance is recommended Analyzing how courts will interpret the standard of care concerning LLM AI usage in medical practice is necessary
15.	Liability for use of artificial intelligence in medicine1 *Price et al., (2024).*	The paper aims to explore liability issues related to AI in healthcare, focusing on evolving tort liability principles It eamines the complexities of causation in AI-related injuries within medical contexts The research discusses the interactions among		The paper discusses evolving liability issues related to AI in healthcare, highlighting uncertainty in legal frameworks as technology advances It emphasizes that liability allocation affects the behavior	Future research should explore the evolving landscape of liability for medical AI as it is still developing and uncertain Investigating the impact of AI on injury rates and liability allocation in healthcare is crucial

		various stakeholders, including healthcare providers and AI developers It highlights the need for policymakers to understand the liability landscape to shape AI adoption effectively The paper also notes potential changes in liability frameworks, particularly in the context of European regulations		of developers and healthcare institutions, influencing AI implementation The integration of AI can reduce overall injury rates, altering liability dynamics among healthcare providers The paper notes that causation in AI-related injuries is complex, complicating liability determinations It suggests that informed parties can signal quality by assuming liability, impacting the overall liability landscape	The role of regulatory bodies, like the FDA, in shaping AI liability standards requires further examination Understanding the interactions among various stakeholders in medical AI liability is essential for effective policy-making Research should address the challenges of demonstrating causation in AI-related injurie
16.	Mixed-Functions IoT devices: a Regulatory and Liability Requirements *Gennari, F. (2024).*	The paper aims to clarify the legal regime applicable to mixed-functions IoT devices It investigates liability issues concerning mixed-functions IoT object The research highlights the social significance of this	The AILP may require modifications to align with the approved AIA, as it currently references the AIA proposal Mixed-functions IoT devices are crucial for smart	The AILDP may require modifications as it references the AIA proposal, not the approved version There is a lack of clarity on minimum harmonization in the AILDP's main	Future research should focus on regulatory requirements for mixed-functions IoT devices in smart homes Investigating the liability rules applicable to mixed-functions

		hybrid category of IoT objects It discusses the regulatory requirements and liability rules for mixed-functions IoT device manufacturers The paper explores the implications of the Product Liability Directive Update (PLDU) on these devices It emphasizes the role of mixed-functions devices in smart homes and rehabilitatio	homes, aiding rehabilitation for an older, digitally literate population The PLDU will be the primary liability regime for mixed-functions IoT objects in consumer-related damages The combination of e-health and consumer functions in devices is not classified as medical under current regulations The AILP's effectiveness depends on member states enacting favorable rules for claimants	text The implications of low-risk AI systems on liability rules need further exploration The regulatory requirements for mixed-functions IoT devices are not fully mapped out The role of mixed-functions devices in smart homes and their interaction with medical IoT devices requires more investigation .	IoT devices is essential Exploring the intersection of consumer and medical IoT devices could clarify compliance duties Understanding the implications of the proposed AI liability directive on mixed-functions IoT devices warrants further study Researching the role of mixed-functions IoT devices in rehabilitation and e-health applications is crucial
17.	A review of the role of artificial intelligence in healthcare *Al Kuwaiti et al., (2023).*	The paper aims to explore the application of AI in various healthcare domains, including diagnostics and patient engagement It addresses the ethical, social, governance, and	AI applications have transformed healthcare, enhancing patient safety and accountability while improving healthcare professionals' acceptance and	here is a lack of empirical data supporting AI-based solutions in healthcare, leading to institutional reluctance in implementation Insufficient experimental data	Future research should focus on a cross-sectional survey of healthcare professionals to gather primary data on key issues addressed in the study

		technical challenges faced by healthcare providers in adopting AI The research emphasizes the importance of effective governance for patient safety and enhancing healthcare professionals' trust in AI It investigates the role of AI in improving healthcare accessibility and efficiency amid challenges like the COVID-19 pandemic The study seeks to compile existing literature on AI's impact in medical research and drug discovery	trust in technology The governance of AI is essential to address regulatory, ethical, and trust issues in healthcare AI technologies are utilized in medical imaging, diagnostics, virtual patient care, and rehabilitation Challenges include data security, privacy concerns, and the need for high-quality health data	validating the efficacy of AI-based drugs in clinical trials is a critical hindrance The quality of existing health data limits AI's effectiveness in addressing healthcare challenges	There is a need to explore the effects of AI tools on clinical trial quality and participant experience Further research is recommended to address sparse and lost tagged data in machine learning models Investigating the governance of AI applications is crucial for enhancing healthcare professionals' trust and patient safety
18.	How are excellence and trust for using artificial intelligence ensured? Evaluation of its current use in EU healthcare *Bimczok et al., (2021).*	The paper aims to evaluate legislative gaps in AI healthcare implementation, focusing on data protection, liability, and transparency It seeks to establish a coherent regulatory framework for efficient AI use in healthcare The introduction of the Health-AI-Directive is	he EU lacks a coherent legal framework for AI in healthcare, impacting efficient implementation A unified AI framework is necessary to address data protection, liability, and transparency	The EU lacks a coherent legally binding regulatory framework for AI in healthcare, addressing data protection, liability, and transparency gaps Current eHealth infrastructure is fragmented across member states, limiting a	Future research should focus on creating a coherent regulatory framework for AI in healthcare, addressing data protection and liability issues Investigating the integration of AI in healthcare requires exploring transparency and

		recommended to ensure trust and excellence in AI applications	The health-AI-Directive is recommended to enhance trust and legal certainty in AI applications Current policies show fragmentation in eHealth infrastructure across member states	structured framework for AI in healthcare There is a need for clear transparency guidelines regarding AI system functionality and capabilities The interdependence of accuracy and transparency in AI applications presents a significant challenge The paper identifies the necessity for a Health-AI-Directive to ensure trust and excellence in AI use in healthcare	robustness in AI applications Research is needed on the governance perspectives involving multi-faceted stakeholders in healthcare AI implementation
19.	Governing AI in the European Union: emerging infrastructures and regulatory ecosystems in health 1 *Minssen et al., (2024).*	The paper aims to evaluate the implications of AI regulations in healthcare, particularly the intersection of the AI Act and GDPR It seeks to identify necessary guidance for developers and users regarding data	The EU is developing a complex regulatory framework for AI, balancing potential harms and data ecosystem development Systematic	Not Discussed	Future research should assess the implications of the governance architecture for AI in health, particularly the intersection of the AI Act and GDPR There is a need for systematic

		obligations under evolving regulations The research intends to analyze the complexities of the regulatory framework governing AI and health data It emphasizes the importance of transparency and accountability in AI systems to protect underrepresented populations	analyses are needed to evaluate AI's implications in health The AI Act introduces a risk classification process for AI systems Challenges exist in defining regulations, especially regarding health applications The GDPR's implementation has led to varied interpretations among member states		evaluation of the transparency and accountability provisions in AI systems used in healthcare Research must address the requirements for diversity and non-discrimination in AI data to prevent biases
20.	General Practitioners' Attitudes Toward Artificial Intelligence–Enabled Systems: Interview Study Buck et al., (2022).	The study aims to investigate determinants influencing GPs' attitudes toward AI-enabled systems in diagnosis It seeks to develop user-centered solutions for successful AI system introduction in primary care The research identifies relationships among categories of GPs' attitudes toward AI-enabled systems	The study identifies GPs' attitudes toward AI-enabled systems in medical diagnosis, revealing concerns and expectations regarding their use AI systems should enhance GPs' efficiency, allowing more time for patient relationships Accountability for	The study's qualitative approach limits generalizability, indicating a need for quantitative research on AI-enabled systems in GP care Participants' varying understandings of AI highlight the need for clearer definitions and education on AI technology	Future research should explore the role of affective attitudes in technology acceptance, which is often neglected in existing theories Investigating liability regulations and their implications for GPs' attitudes toward AI-enabled systems is a promising area Research should

			AI-induced errors is debated between physicians and healthcare organizations		focus on how to proactively promote GPs' attitudes toward AI-enabled systems in healthcare Examining the integration of user groups' attitudes and needs is essential for user-centered design in AI systems Further studies could assess the impact of AI on the physician-patient relationship and address concerns about automation bias
21.	Defining medical liability when artificial intelligence is applied on diagnostic algorithms: a systematic review *Cestonaro et al, (2023).*	The paper aims to review medical professional liability related to AI-based diagnostic algorithms from 2020 to 2023 It seeks to address the growing attention on liability issues in AI-related errors and patient damage The research highlights the need for a regulatory framework governing AI liability and safety	The study included 23 articles, primarily perspectives and reviews, with only one systematic review identifi AI's application in healthcare raises liability concerns, necessitating clear regulatory frameworks The complexity and opacity of AI	The paper notes a lack of in-depth analysis on liability issues related to AI errors in healthcare There is insufficient regulation governing liability in the AI supply chain and for end-users The impact of AI on the doctor-patient relationship and empathy	Future research should focus on the regulatory framework for AI in medicine, addressing liability issues and responsibilities in case of errors Investigating the impact of AI on the doctor-patient relationship and the potential loss of empathy is essential

		standards	systems challenge existing liability models Over-reliance on AI may lead to de-skilling and desensitization among healthcare professionals	requires further exploration Gaps exist in understanding the implications of using unrepresentative populations in AI development The potential for health disparities due to AI algorithms needs more investigation .	The implications of AI's role in medical decision-making and the risk of de-skilling healthcare professionals require further exploration Research should examine the effectiveness of proposed legal solutions, such as conferring personhood to AI devices Addressing potential liability gaps in black-box AI systems is crucial for future studies
22.	First Do No Harm: Legal Principles Regulating the Future of Artificial Intelligence in Health Care in South Africa *Donnelly, D. L. (2022).*	The paper aims to examine legal reform areas related to AI in health care, focusing on regulatory frameworks for software as a medical device It proposes developing a national policy framework of ethical principles to complement existing health care legislation The research	The paper identifies the need to update the regulatory framework for software as a medical device in health care It highlights the restrictive nature of current HPCSA guidelines, which may hinder technological innovation	The paper highlights the need for updated regulatory frameworks for AI in healthcare, indicating a gap in current laws and guidelines There is a lack of a national AI strategy in South Africa, which contrasts with other countries'	The regulatory framework for software as a medical device needs updating to adequately regulate new technologies Consideration should be given to developing a statutory scheme for strict liability and mandatory insurance The need for

		highlights the need for proactive regulatory engagement to ensure laws are contextually appropriate for South Africa	The research suggests developing a statutory scheme for strict liability and mandatory insurance for technology developers	advancements The existing common law principles may not adequately address medical negligence related to new technologies, suggesting a gap in legal redress	reform in regulatory oversight mechanisms is essential for AI in health care
23.	Promise and Provisos of Artificial Intelligence and Machine Learning in Healthcare *Bhardwaj, A. (2022).*	The paper aims to explore the transformative potential of AI and ML in healthcare and medicine It discusses the challenges and caveats in implementing ML technologies in clinical settings The research evaluates the cost-benefit and value proposition of novel healthcare technologies	AI and ML can transform healthcare but cannot replace empathetic clinicians Cost-benefit issues of ML in healthcare need further exploration ML applications include enhanced diagnostics and personalized medicine ML can analyze speech patterns to detect psychiatric conditions	Challenges in achieving broader acceptance and application of ML in healthcare remain unaddressed The cost-benefit relationship of ML in healthcare needs further exploration Issues of data ownership and consumer privacy require regulatory development Reliability of input data and interpretation of output data are significant concerns	Future research should address the reliability of input data and interpretation of output data in AI applications Investigating consumer privacy and liability issues due to potential data breaches is essential Enhancing patient satisfaction and affordability in clinical care remains a critical area Exploring the cost-benefit analysis of AI and ML in healthcare is necessary Further studies on the integration of AI in clinical care while maintaining

					human interaction are needed
24.	National study on use of artificial intelligence in breast disease and cancer *Emiroglu et al., (2022),*	The study could not perform subgroup analysis due to low participant numbers, indicating a gap in detailed demographic insights The survey did not include doctors from other specialties involved in breast cancer treatment, limiting the comprehensiveness of the findings	The study found that 49.4% of participants had little knowledge of AI in breast disease and cancer care 70.3% of respondents identified rapid diagnosis as the main advantage of AI 40.1% believed AI would moderately improve their specialization in breast diseases Participants expressed concerns about medical errors and liability issues related to AI	he study could not perform subgroup analysis due to low participant numbers, indicating a gap in detailed demographic insights The survey did not include doctors from other specialties involved in breast cancer treatment, limiting the comprehensiveness of the findings There is a need for robust studies on the practical application of AI in clinical settings, highlighting a gap in current research	Future research should focus on robust studies for practical applications of AI in clinical settings Investigating the integration of AI technologies in breast disease management is essential Further exploration of AI's impact on radiology within breast healthcare is needed Addressing concerns regarding medical errors and liability issues related to AI use is crucial Research should evaluate the long-term effects of AI on patient care and treatment outcomes
25.	Ai And Liability in Medicine: The Case of Assistive-Diagnostic Ai *Rimkutė, D. (2024).*	The paper aims to explore consumer expectations in assistive-diagnostic AI contexts It discusses the implications of	The paper analyzes the liability of healthcare institutions and product liability concerning	The paper lacks clarity on how to measure consumer expectations in assistive-diagnostic AI There is	Future research could explore the legal implications of AI in healthcare, particularly regarding liability frameworks and

		product liability and regulatory frameworks for AI The research examines the tangibility of assistive-diagnostic AI software as a product	assistive-diagnostic AI, emphasizing negligence scenarios It discusses the implications of AI's autonomy on the chain of causation in liability cases The research highlights the importance of adequate data quality and diversity in AI training to prevent bias	insufficient exploration of the implications of design defects in AI systems The challenges in establishing liability for AI-related cases remain inadequately addressed The evolving nature of AI and its impact on design defect assessments is not thoroughly analyzed .	patient harm Investigating the effectiveness of the AILD and PLD proposals in addressing liability challenges is essential Research may focus on the organizational responsibilities of healthcare institutions in mitigating AI-related errors The impact of assistive-diagnostic AI on misdiagnosis and liability attribution warrants further examination Exploring compensation mechanisms for victims in AI-related cases could enhance understanding of liability challenges
26.	Advantages and ethics of artificial intelligence in plastic and reconstructive surgery *Treger et al., (2025).*	The paper aims to explore the potential benefits of AI in plastic and reconstructive surgery practice It discusses the ethical considerations and	ChatGPT performs better than early trainees on Plastic Surgery In-Service Exams but struggles with nuanced clinical scenarios	The paper highlights uncertainty regarding AI's safety and actual utility in plastic surgery Ethical	Future research should explore AI's role in enhancing surgical precision and improving patient safety in plastic sur Investigating the

		policies needed for AI's use in healthcare The manuscript addresses the uncertainty surrounding AI's safety and utility in plastic surgery It advocates for a cautiously optimistic approach to incorporating AI in surgical practices	AI in plastic surgery raises ethical and legal concerns, necessitating careful regulatio Malpractice liability may involve multiple parties, including surgeons and AI developers Administrative tasks in plastic surgery can be automated, improving efficiency and patient care	considerations and necessary policies for AI regulation remain underexplored There is a lack of clarity on liability issues if AI causes adverse outcomes The paper suggests a need for greater understanding of AI's inner workings to build trust	ethical implications and liability models for AI use in healthcare is essential The development of AI-driven surgical robots and navigation systems requires further exploration
27.	AI assessment tools for decision-making on telemedicine: liability in case of mistakes *Clavijo, S. (2024).*	The paper aims to explore the implementation of AI as a medical decision support tool for telemedicine It investigates liability issues arising from erroneous predictions by AI systems The research discusses the regulatory framework for AI in healthcare, particularly in Europe It examines the explainability of AI systems to enhance physician trust and	The implementation of AI as a medical decision support tool raises liability questions for erroneous predictions in telemedicine The proposed regulatory framework suggests compensation for damages should align with defective product directives AI systems in	Not found	Future research could explore the effectiveness of ML-based tools in managing non-urgent patient demand and telemedicine applications Investigating the legal implications of AI system errors in medical decision-making is essential The explainability of AI systems in clinical settings warrants further

		decision-making	healthcare undergo strict evaluations to ensure compliance with safety and marketing requirements The study highlights challenges in liability concerning AI systems used for medical decision support		examination to enhance physician trust.
28.	AI in Radiology: Navigating Medical Responsibility Contaldo et al., (2024),	The paper aims to analyze the significance of responsibility in jurisprudence, focusing on accountability, culpability, and liability in AI usage It emphasizes the legal aspects of AI in healthcare, highlighting the need for robust liability frameworks The research explores the evolving doctor-patient relationship in the AI era, transitioning to a trilateral model	The primary responsibility for errors remains with the physician, with potential shared liability with developers under medical device liability frameworks AI's integration in healthcare necessitates robust liability frameworks and transparent communication about AI's role Effective AI use requires understanding data dynamics,	the paper highlights the need for robust liability frameworks in AI applications within radiology, indicating a gap in current legal standards There is a lack of understanding regarding the "black box" nature of AI systems, which complicates legal accountability The research does not address the implications of AI decision-making on physician autonomy and responsibility in	Future research should explore the integration of AI in enhancing diagnostic accuracy and clinical management Investigating the ethical and legal challenges of AI in healthcare is crucial for comprehensive integration The concept of "Hybrid Intelligence" in radiology warrants further exploration to enhance human and AI collaboration Understanding the implications of

			despite the "black box phenomenon" complicating result interpretation	clinical practice	"system transparency" and "black box" theories in AI decision-making is essential Research should focus on developing robust liability frameworks for AI systems in medical practice The dynamics of data used in AI evaluations and their impact on clinical decisions require further investigation
29.	A New Argument for No-Fault Compensation in Health Care: The Introduction of Artificial Intelligence Systems *Holm et al., (2021*	The paper aims to explore no-fault compensation schemes for AI systems in healthcare settings It analyzes the challenges of integrating AI into fault-based compensation systems The research argues that no-fault systems can more effectively address issues arising from AI systems	The paper argues that no-fault compensation schemes are more effective for AI-related issues than fault-based systems It highlights the challenges of integrating AI systems into traditional fault-based compensation frameworks The analysis is not jurisdiction-	The paper highlights the challenge of establishing liability for AI classification errors due to lack of explanation on error origins There is a concern regarding the adequacy of training datasets, particularly for under-represented groups The paper notes the limitations of	Future research could explore the implications of strict liability in AI systems within healthcare settings Investigating the impact of resource constraints on AI research and development is essential Examining the effectiveness of a no-fault system for addressing medical errors made by AI is a potential area

			specific but relies on general legal principles of tort law The paper discusses the opacity of AI decision-making and its implications for liability	comparing AI systems to human decision-makers, suggesting a need for clearer standards It discusses the implications of resource constraints on AI research and development, indicating a gap in equitable access The abstract mentions the need for understanding tort/negligence approaches in the context of AI in healthcare, indicating a gap in legal frameworks	Research could focus on the legal frameworks surrounding AI negligence claims and their applicability The development of standards for evaluating AI system performance in clinical settings warrants further investigation Analyzing the role of data quality and system errors in AI decision-making could provide insights
30.	Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI? *Sullivan et al., (2019)*	The objective is to evaluate physicians and medical students' attitudes and perceptions regarding AI applications in healthcare The study aims to analyze familiarity with AI among medical professional It seeks to assess the readiness for introducing AI into the medical curriculum	The paper discusses AI's role in healthcare, highlighting its use in predictive algorithms for patient care and risk assessment It addresses complex legal questions regarding liability for healthcare professionals and technology	Not addressed in the paper	Future research could explore legal implications of AI in medical malpractice and products liability Investigating modifications to current tort frameworks for AI liability is essential The concept of AI personhood warrants further examination in

		The research intends to improve clinical care delivery and operational efficiencies through AI	manufacturers when AI recommendations are unexplainable The authors propose legal solutions for AI liability, including shared responsibility among all parties involved in AI implementation		legal contexts Research on common enterprise liability theories related to AI could provide insights Understanding the black-box nature of AI systems is crucial for liability assessments

Analysis of Phase II

AI in healthcare is a rapidly growing area of research, particularly in the past decade. As AI systems are increasingly used in diagnostics, robotic surgeries, clinical decision-making, and hospital administration, legal liability and accountability issues have become crucial. The increasing dependency on the said technologies has entailed a corresponding growth in the legal scholarships, particularly on the subject of the facial intelligence liability . Yet the literature view points out the significant theoretical doctrinal and practical ignas in dealing with the challenges. In particular, the terms of surgical and non surgical medical context, where the early literature is mostly focused on the technical capabilities and limitations on the artificial intelligence in healthcare and medical care. The investigation highlighted that efficiency, precision and promise of the machine learning and the autonomous technology to regularise the patient care the ethical research in this area has focused. On the issue of data privacy algorithm biasness. Patient consent, particularly van involving a non-interpretable model Although they offer important insight into the larger socio technical implications of artificial intelligence, there are generally not literature and legal depth, which respect to the normative liability structures

The increasing dependence on said technologies has entailed a corresponding growth in legal scholarship, particularly on the subject of liability for harm caused by AI. Yet, the literature review points out significant theoretical, doctrinal and practical lacunas in dealing with such challenges, in particular in terms of surgical and non-surgical medical contexts.

Early literature is mostly focused on the technical capabilities and limitations of AI in health and medical care. These investigations highlight the efficiency, precision, and promise of machine learning and autonomous technologies to revolutionize patient care. Ethical research in this area has also been focusing on the issues of privacy of data, bias of algorithms, patient consent, particularly when involving non-interpretable "black-box" models. Although they offer important insight into the larger socio-technical implications of AI, they are generally not literature in legal depth with respect to normative liability structures.

The law literature remains in its infancy, with piecemeal studies retrofitting the traditional doctrines of tort law, medical malpractice and product liability to apply to AI. One group of scholars suggests modifying tort law, on the basis of already established tort theories like strict liability or fault-based liability; another group argues for the development of completely new statutory systems or an AI-specific system. The preliminary views offered in the PLD (Product Liability Directive) and AILD (AI Liability Directive) as well as isolated judicial commentary in common law jurisdictions provide initial guidance, yet consensus on such matters as causation, foreseeability, and the distribution of responsibility among innovators, institutions, and players still remains largely elusive. Indeed, limited research has compared the legal perspectives and literature across jurisdictions or has conducted empirically based studies to ascertain the views of stakeholders, particularly: clinicians, lawyers, parents, and service providers.

4. RESEARCH GAP

After the Analysis of both quantitively and qualitative research around the Application of artificial intelligence in healthcare, it has been found that the ethical and legal framework on surgical and non-surgical process in the healthcare establishments is not clear on case of adoption of AI, whereas the liability model and their application in emerging Healthtech is not touched by the researcher. Further, there is a dearth of empirical legal studies and case law that analyze how courts perceive errors or negligence cause with the application of software in the healthcare establishment, while algorithmic bias and discrimination and minority patients Remain underregulated in case of artificial intelligence.

The approach to set the Degree of liability effective measure, strategies or guideline towards the liability in AI driven healthcare establishment of Involved stakeholders is still not clear and no attempt made to do the compreshive analysis of Traditional liability model and case analysis. While there are numerous studies on AI's impact in healthcare, few provide a comprehensive legal analysis of liability attribution in both surgical and non-surgical AI applications. Most research is normative or theoretical, lacking structured frameworks or empirical validation.

Limited Comparative Legal Analysis: There are insufficient exploration of how the different jurisdictions particularly in developing countries are adapting liability principles to accommodate AI's evolving role in healthcare.

There is a paucity of empirical studies assessing how legal professionals, healthcare providers, and policymakers perceive the growing complex web AI-induced liability. The current state of research also lacks a model liability framework tailored to the technological attributes of AI, such as autonomy, opacity, and adaptiveness, especially when integrated with existing medical negligence and tort principles.

5. RESEARCH OBJECTIVES

Bases on the gap identified from the literature review, the research work proposed to cover the following objectives

RO1: To Understand the application of artificial intelligence technologies in healthcare establishments in surgical and non-surgical use case.

RO2: To analyze the existing legal regulations and judicial approaches for assigning the liability in case of harm in healthcare.

RO3: To critically evaluate the measures, policies, and sector specific frameworks adopted by India, EU, US, Japan regarding the implementation of AI in healthcare.

R04- To examine how the absence of AI specific framework contributes the legal uncertainty among key stakeholder and

RO5: To purpose a comprehensive framework and recommend strategies that to promote clarity of liability rules for AI-driven healthcare establishments for innovation and trustworthy AI.

6. HYPOTHESIS

For this research the researcher proposed to testify

H1- Existing healthcare liability models are inadequate to address the novel challenges posed by AI in healthcare, particularly in attributing liability and establishing causation."

H2- The absence of a dedicated regulatory framework for AI liability in healthcare establishment creates legal uncertainty among stakeholders and constitutes a barrier to the wider adoption of AI technologies.

7. RESEARCH QUESTION

RQ1: What are the primary applications of AI in surgical and non-surgical healthcare, and what potential benefits and liability risks arise from their use?

RQ2: To what extent are traditional Liability model address the issues posed by AI in healthcare establishment?

RQ3: How do different jurisdictions (India, EU, USA, Japan) approach towards liability in AI-assisted healthcare?

RQ4: How does the absence of a dedicated AI liability framework in healthcare contribute to legal uncertainty among stakeholders, and to what extent does this uncertainty hinder the

adoption of AI technologies in clinical practice?

8. RESEARCH METHODOLOGY

This research will adopt the Mixed methodology to conduct the study. For the purpose of Legal aspect of AI in healthcare the researcher will use the Non empirical research method this include the Legal analysis and comparative analysis where the data will be covered from the both primary and secondary sources which will include the policies, legislations, research paper and reports from the various relevant sources. Whereas to understand the implication of AI risk management in the healthcare establishments and liability issue for the better recommendations. The researcher will adopt the empirical research method where primary data will be collected through the experts, policymakers and academicians via using a research Technique Interview and Questionnaire.

8.2 Target Group

The target population will include the various stakeholder involved in the adoption of healthcare and policymaking. For the purpose of this study the target population will be Academician, Policymaker, AI researcher and technology developers.

8.3 Sampling Size and Sampling Technique

The sample size will be selected by using the *Cochran, W. G. (1977)* As the Infinite population are selected for the research it will use the Cochran sampling size that is 385 responses with the 95 % confidence level and 5 % error.

8.4 Tools for Collection and analysis of Data

The primary data will be collected through the questionnaire and interview where the survey will be conducted with the participant to collect their opinion and perception about the Adoption of AI in healthcare and Liability complexity.

Collection of Data- for the purpose of collection of data the research will use the GOOGLE FORM to circulate the questionnaire and collect responses.

Data Analysis- For the purpose of cleaning and analysis of data and to find the relevant result the study will adopt the NVivo or SPSS software. The relevant qualitiave test will be adopted to find the relevance in the data.

9. EXPECTED OUTCOME

The thorough analysis of existing liability frameworks, which would highlight effectiveness and limitations. With the comparative study of international regulations, it will offer insights into how different countries address AI-related law in healthcare sector and liability.

This will offer practical Evidence based recommendations for policy and regulatory strategies to ensure effective oversight and responsible AI use to encourage innovation.

valuable knowledge to the fields of healthcare law, technology regulation, and AI ethics, benefiting academics, legal practitioners, policymakers, and healthcare industry will be marked. Ultimately, the study seeks to create an evidence-based, legally robust foundation for regulating emerging healthcare technologies, ensuring patient safety, professional accountability, and technological innovation under a clearly defined legal structure.

10.TENTATIVE PROPOSED CHAPTALIZATION

Chapter 1: Introduction

Chapter 2: Applications of Artificial intelligence in Healthcare and Liability Implications

Chapter 3: Existing Legal Framework and Judicial Approaches towards Liability in Healthcare Establishment.

Chapter 4: Comparative Analysis of Emerging AI Liability Frameworks.

Chapter 5: Empirical Study on Stakeholder Perceptions of Liability and the Impact of Absence of AI-Specific Frameworks in Healthcare.

Chapter 6: Findings, Recommendations And Conclusion

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Proposed Month-wise plan of work and targets to be achieved Ghantt Chart

S. No.	ACTIVITIES	Months-Year														
		June 2025	August 2025	October 2025	November 2025	December 2025	Jan 2026	Feb 2026	March 2026	April 2026	May 2026	June 2026	July 2026	August 2026	Sep - Nov 2026	December 2026
1	Thesis Proposal defense															
2	Extended Literature															
3	Questionnaire designing															
4	Pilot testing and refinement															
5	Data collection															
9	Data preparation															
10	Data analysis & Results															
11	Report writing: Chapter1: ……..															
12	Report writing: Chapter 3:															
14	Thesis Writing, Publications and Other															
15	Thesis Submission															